specification showing the effect of the intermediate on the final product. If no such evidence exists then there is no unity on the basis of an intermediate-final product relationship.

Biotechnological Inventions

10.52 *Example 32: Multiple Structurally and Functionally Unrelated Polynucleotides*

Claim 1: An isolated polynucleotide selected from the group consisting of the nucleotide sequences SEQ ID NOs: 1-10.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The description discloses that the claimed polynucleotides are 500 bp cDNAs obtained from a human liver cDNA library. The polynucleotides are structurally different and can be used as probes to obtain full-length DNAs, although there is no description of the function or biological activity of the corresponding proteins. Furthermore, the polynucleotides claimed are not homologous to each other.

There is no prior art available. A human liver cDNA library had not been established before.

The polynucleotides of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

In this example, the description fails to disclose that all of the polynucleotides SEQ ID NOs: 1-10 share a common property or activity. While each sequence may serve as a probe to isolate its own respective full length DNA, due to the lack of homology between SEQ ID NOs: 1-10, a probe derived from SEQ ID NO: 1 cannot be used to isolate SEQ ID NOs: 2-10, respectively.

Moreover, since the polynucleotides are not homologous to each other, they fail to share a common structure i.e., a significant structural element. The sugar-phosphate backbone cannot be considered a significant structural element, since it is shared by all nucleic acid molecules. Therefore, the 10 polynucleotide molecules do not share any significant structural element and cannot be considered as having the same or corresponding technical feature.

The mere fact that polynucleotide fragments are derived from the same source (human liver) is not sufficient to meet the criteria for unity of invention. The polynucleotides fail to share a common property or activity and fail to share a common structure. Since neither of these two requirements is met, the group of polynucleotide molecules claimed does not meet the requirement of unity of invention (*a priori*).

One possible grouping would be:

Inventions 1-10: Polynucleotides having SEQ ID NOs: 1-10.

10.53 *Example 33: Multiple Structurally and Functionally Related Polynucleotides*

Claim 1: An isolated polynucleotide selected from the group consisting of the nucleotide sequences SEQ ID NOs: 1-10.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The facts are the same as Example 32 except that the claimed polynucleotides all share a significant structural element and their corresponding mRNAs are expressed only in

the hepatocytes of patients with disease Y. The corresponding mRNAs are not expressed in the hepatocytes of healthy individuals.

There is no prior art available. The shared structural element had not been identified before, nor had any link been established between genes expressing mRNA containing that structural element and patients afflicted with disease Y.

The polynucleotides of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

In this example, the description discloses that SEQ ID NOs:1-10 share a common property, that is, expression of an mRNA present only in patients afflicted with disease Y. Moreover, SEQ ID NOs: 1-10 share a significant structural element that is essential to the common property, i.e., a probe comprising the shared structural element can detect the mRNA of patients afflicted with disease Y. Since both of these requirements are met, the group of polynucleotide molecules claimed meets the requirement of unity of invention (*a priori*).

10.54 *Example 34: Functionally Unrelated Single Nucleotide Polymorphisms (SNPs)*

Claim 1: An isolated nucleic acid molecule comprising SEQ ID NO: 1 with a single polymorphic change at one of the positions as shown below:

Polymorphism	*Position*	*Change from SEQ ID NO: 1 to:*
1	*10*	*G*
2	*27*	*A*
3	*157*	*C*
4	*234*	*T*
5	*1528*	*G*
6	*3498*	*C*
7	*13524*	*T*
8	*14692*	*A* .

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

According to the description, SEQ ID NO: 1 is 22,930 nucleotides in length. The SNPs 1-8 are not characterized, that is, no common property or activity has been disclosed.

SEQ ID NO: 1 has been described in the prior art but no specific function has been identified.

The polynucleotides of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

In this example, the description fails to disclose that all of the SNPs 1-8 share a common property or activity. The fact that all point mutations are within a defined sequence (SEQ ID NO: 1) is not sufficient to establish unity of invention since SEQ ID NO: 1 has already been described in the prior art, and no functional relationship exists among the different SNPs claimed. For this reason, the SNPs of claim 1 lack unity of invention.

One possible grouping would be:

Inventions 1-8: SNPs 1-8.

10.55 *Example 35: Molecules Which Share a Common Function not Linked to a Common Structure*

Claim 1: A fusion protein comprising carrier protein X linked to a polypeptide having SEQ ID NO 1, 2, or 3.

The description discloses that carrier protein X is 1000 amino acids in length and functions to increase the stability of the fusion proteins in the blood stream. SEQ ID NOs: 1, 2, and 3 are small epitopes (10-20 residues in length) isolated from different antigenic regions of E.coli. *SEQ ID NOs: 1, 2, and 3 do not share any significant common structure.*

Both the structure of protein X and its function as a carrier protein are known in the prior art. Fusion proteins that generate an antigenic response to E. coli *are known in the prior art.*

The fusion proteins of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

In this example, the only common structure shared by the fusion proteins is carrier protein X. The fusion proteins share a common property, i.e., generation of an antibody response specific for *E. coli*. However, immunization with the carrier protein alone does not result in the common property; SEQ ID NO: 1, 2, or 3 is required for this property.

No special technical feature exists among the three fusion proteins. The fact that all the fusion proteins have a common property is not sufficient to establish unity of invention because (1) SEQ ID NOs: 1, 2, and 3, which impart the common property, do not share a significant structural element, (2) the common structure, carrier protein X, does not impart the common property, and (3) fusion proteins that generate an antigenic response specific for *E. coli* are known in the prior art.

One possible grouping would be:

Invention 1: Fusion protein comprising carrier protein X and SEQ ID NO: 1.

Invention 2: Fusion protein comprising carrier protein X and SEQ ID NO: 2.

Invention 3: Fusion protein comprising carrier protein X and SEQ ID NO: 3.

10.56 *Example 36: Multiple Nucleic Acid Molecules Which Share Common Structure and Encode Proteins with Common Property*

Claim 1: An isolated nucleic acid selected from SEQ ID NO: 1, 2, or 3.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The description discloses that the three nucleic acids encode dehydrogenases that include a conserved sequence motif defining the catalytic site and the dehydrogenase function of these proteins. The three nucleic acids were isolated from three different sources (mouse, rat, and human). The description clearly shows that these three nucleic acids are homologous based upon their overall sequence similarity (85-95% identity) at both the nucleotide and amino acid sequence levels.

The prior art describes a nucleic acid molecule isolated from monkeys, which has high sequence similarity (e.g., 90%) to SEQ ID NO: 1. The monkey nucleic acid encodes a dehydrogenase that includes the catalytic site defined by the conserved motif.

The nucleic acids of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

Rule 13.2 requires that the technical feature shared between the inventions defines a contribution over the prior art.

A same or corresponding technical feature shared among the claimed nucleic acid molecules resides in their common property (encoding dehydrogenases) and their shared structural element that is essential to the common property (the conserved motif). However, a nucleic acid molecule which encodes a dehydrogenase and contains the shared structural element has already been isolated from a different source (monkeys). Thus, the technical feature is not special because the functional and structural similarity between the claimed molecules cannot form the contribution that the group of inventions as a whole makes over the prior art. Therefore, unity of invention is lacking (*a posteriori*).

On the other hand, if the only prior art available disclosed a nucleic acid molecule encoding a dehydrogenase that lacked the catalytic site defined by the conserved sequence motif, the technical feature would be special and SEQ ID NOs: 1, 2, and 3 would have unity of invention.

A possible grouping would be:

Invention 1: Nucleic acid of SEQ ID NO: 1

Invention 2: Nucleic acid of SEQ ID NO: 2

Invention 3: Nucleic acid of SEQ ID NO: 3

10.57 *Example 37: DNA Encoding Receptors with Partial Structural Identity and Asserted Common Property*

Claim 1: A polynucleotide encoding a guanosine triphosphate-binding protein coupled receptor (GPCR) comprising a nucleotide sequence selected from the group consisting of the odd-numbered SEQ ID NOs from SEQ ID NO: 1 to SEQ ID NO: 2069.

The description identifies a conserved sequence of 15 amino acid residues found in several known GPCR molecules that is asserted to be essential to the GPCR function. A consensus polynucleotide sequence encoding the conserved amino acid sequence was generated. A database containing human genome sequences was searched using the consensus polynucleotide sequence. Using this system, 1035 polynucleotide sequences were identified, which are asserted to encode GPCR molecules that include the conserved sequence.

The prior art discloses human GPCR molecules that contain the conserved sequence of 15 amino acid residues, as well as the polynucleotide sequences that encode the conserved 15 amino acid sequence.

The common technical feature among the 1035 polynucleotide sequences is the consensus polynucleotide sequence that encodes the common sequence of 15 amino acid residues. This technical feature is not special because the consensus polynucleotide sequence was known and therefore cannot form the contribution that the group of inventions as a whole makes over

the prior art. Consequently, the 1035 different polynucleotides lack unity of invention (*a posteriori*).

One possible grouping would be:

Inventions 1-1035: Polynucleotides based on SEQ ID NOs: 1-2070 (odd-numbers)

If the description did not assert, or it was not readily apparent, that the conserved sequence of 15 amino acid residues was essential to the GPCR function, unity of invention could be lacking in the absence of any relevant prior art.

On the other hand, given the assertion in the description, in the absence of the prior art in the example, the groups would have had unity of invention.

10.58 *Example 38: Method of Screening and Compounds Identified by the Method*

Claim 1: A method to identify compounds that are antagonists of receptor R comprising the steps of contacting cells expressing on their outer membrane receptor R with its natural ligand; observing the binding of the ligand; contacting said cells bound to said ligand with a candidate compound selected from a library of compounds; and observing any change in the binding of the ligand.

Claim 2: Compound X, having formula 1.

Claim 3: Compound Y, having formula 2.

Claim 4: Compound Z, having formula 3.

Receptor R and its natural ligand are proposed as a drug target. Compounds that antagonise receptor R are proposed to have physiological effects that may be useful in therapeutic treatment. The aim is to identify lead compounds as a basis for further screening and testing of combinatorial libraries. A library is described as providing many possible structurally different compounds. Examples show that the method of claim 1 can be used to identify compounds affecting the physiological effect of binding of the natural ligand to the receptor. Only compounds X, Y and Z were shown to have such effects, but they do not appear to share a significant structural element. The description is silent with regard to the both the relationship between the structure and activity of the claimed compounds and the relationship between the structure of receptor R and the structure of the compounds.

Receptor R, its biological function, and its natural ligand are known in the prior art. No compounds that function as antagonists of receptor R are known.

The technical feature of method claim 1 resides in the step of observing the effect of the candidate compounds on ligand binding in a screening assay. Neither the same nor a corresponding special technical feature is present in any of compounds X, Y, or Z. No manufacturing relationship exists between the screening method and the claimed compounds. Further, the screening method is not a method of using claimed compounds X, Y, and Z. In the absence of any teaching as to the structure required for a compound to act as a receptor R antagonist, there is no single general concept that links the method to the claimed compounds. Thus, unity of invention is lacking (*a priori*).

Compounds X, Y, and Z would be regarded as having the same or corresponding technical feature if they had a common property or activity, and shared a significant structural element that is essential to the common property or activity. While compounds X, Y, and Z do share the common property of antagonising receptor R, there is no teaching as to a shared significant structural element, and hence, there is no disclosure of the same or corresponding technical feature.